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EXAMINER

SAUNDERS, DAVID A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 01/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

052,234

Applicant(s)

DEBART et al

Examiner

SAUNDERS

Group Art Unit

P644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Priority Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 10/6/03.
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-48 is/are pending in the application.
- Of the above claim(s) 48 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-47 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

Office Action Summary

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Claims 1-48 are pending.

Applicant's election with traverse of Group I (claims 1-47) in Paper filed 10/6/03 is acknowledged. The traversal is on the ground(s) that there is no added search burden for the examiner to search for the product by process claim. This is not found persuasive because the product by process claim is essentially unsearchable without a recitation of any physical and/or chemical characteristics of the obtained product. Patent disclosures of injectable IgG preparations having reduced aggregates, reduced contamination of various enzymes, inactivated viruses, etc. are a dime a dozen. It is impossible for the examiner to guess how applicant might wish to claim his obtained product, in terms of IgG purity, contaminant levels, viral levels etc. From the disclosure, there would be numerous permutations and combinations of such variables which could be used to describe the product obtained. For the examiner to search for a product having unknown characteristics would constitute an undue burden.

The requirement is still deemed proper and is therefore made FINAL.

The disclosure is objected to because of the following informalities: At page 10, line 11 the 6 digit Patent No. is spurious.

Appropriate correction is required.

Claims 1, 19-20 and 24 are objected to because of the following informalities: In these claims "pasteurization" and "pasteurized" should begin with a capital. Appropriate correction is required.

Claim 46 is objected to because of the following informalities: In step a) "between" is surplusage. Appropriate correction is required.

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Claim 46 is objected to under 37 CFR 1.75(i), as being of improper form for failing to indent step b).

Claims 1-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the preamble and step f) recite "human gammaglobulin G" while step a) recites "IgG". Consistent terminology in this claim and all dependents is required.

In claim 1, steps a)-d) and f) use "ing" verbs, while step e) uses no verbs. Parallel construction would be appropriate by reciting – Pasteurizing – and -- treating – in step e); all dependent claims must appropriately correct these terms. Likewise, in claims 44 and 46, "diafiltration", "concentration" and "nanofiltration" should appear as "ing" verbs.

Claim 21 recites the limitation "the sugar alcohol" in line 3. There is insufficient antecedent basis for this limitation in the claim. Dependency from claim 20, in lieu of 19, would be appropriate.

In claims 42 and 46, it is not clear as to after what step of the base claims, the additionally recited steps are to be conducted.

Prior Art of interest:

Hirao et al (4,876,088) teach a method in which sorbitol is present as a stabilizer during a heat treatment to inactivate viruses (col. 5). They also teach use of sorbitol as a stabilizer of the final product (col. 6).

Sarno et al (5,177,194) teach a method having certain steps in common with that instantly – including suspension of a Cohn Fraction ppt. (col.2), pptn. of contaminants with PEG (col. 2),

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viral inactivation (col. 30), anion exchange (col. 5), and ultrafiltration (col. 5). The suspending step does not employ a carbohydrate or sugar alcohol. Also viral inactivation is conducted prior to anion exchange. Also instant step f) is not taught by Sarno et al.

Hirao et al (6,124,437) teach suspension of a Cohn Fraction. Sorbitol is added and the preparation is heated to inactivate viruses. PEG is then used to ppt. IgG. Resolubilized IgG is then treated by anion exchange. The resulting product is stabilized with sorbitol. See examples.

Hirao et al (6,159,471) teach (Example 1) resuspension of a Cohn Fraction. Sorbitol is added and the preparation is heated to inactivate viruses. PEG is then used to ppt. contaminants. The resulting supe is then ultrafiltered and treated with an anion exchanger. The resulting product is stabilized with sorbitol.

Laursen et al (US 6,281,336 corresponding to WO 99//64462) essentially show the instant method except for the facts that step a) of Laursen et al suspends an IgG precipitate in a solution which does not contain a carbohydrate or sugar alcohol, and that instant step f) is not taught by Laursen et al.

Hooper et al (WO 84/00891) show a method (page 12 and examples) which has certain steps in common with that instantly. They teach providing a stabilizer during anion exchange and/or ultrafiltration steps. (e.g. Summary at page 3). The stabilizer can be sorbitol (page 8).

Mamidi et al (6,441,144) teach preparation of IgG from a suspended Cohn Fraction. PEG is used to both precipitate contaminants and then to precipitate IgG. Thus prepared IgG is then treated by anion exchange and then a solvent/detergent inactivation; this is followed by a heat treatment viral inactivation and then cationic exchange or a second PEG precipitation (col. 4, line 53-col. 5, line 3). Sorbitol can be present during the heating viral inactivation step; sorbitol is

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also used to stabilize the final product. Mamidi et al do not teach use of sorbitol in the resuspension of the Cohn Fraction. Also, they do not teach an ultrafiltration step.

None of these references alone or together motivates the instantly recited order of steps.

Claims 1-47 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Mon-Thu from 8:00 to 5:30. The examiner can also be reached on alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-xxxx. The fax phone number for the organization where this application or proceeding is assigned is 571-272-xxxx.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-xxxx.

Typed 1/6/04 DAS

David A Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~/644